K063034
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Air-Flex with Auto-Distraction

1. Submitter's Name and Address

1.1	Submitter's Name:	Hill Laboratories
1.2	Address:	3 Bacton Hill Rd
1.3	City, State, and Zip:	Frazer, PA 19355

2. Contact Person

2.1	Name:	Brady Aller
2.2	Title:	Sales/Service Manager
2.3	Telephone:	(610) 644-2867
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3, Manufacturing Facility Address

3.1	Manufacturer:	Hill Laboratories
3.2	Address:	3 Bacton Hill Rd
3.3	City, State, and ZIP:	Frazer, PA 19355

4. Establishment Registration Number

Est. Registration Number: 2510425

5. Date of Summary Preparation

Date of Preparation: September 21, 2006

6. New Device Details

6.1	Proprietary or Trade Name:	Air-Flex with Auto-Distraction
6.2	Common Name:	Multi-function physical therapy table
6.3	Classification Name:	Table, Physical Therapy, Multi Function

7. Class and Reference

7.1	Class:	Class II
7.2	Reference:	21 CFR 890.5880.

8. Product Code

Product Code: JFB

9. Device Description

The AIR-FLEX with AUTO-DISTRACTION is a modification of the AIR-FLEX table originally cleared under K932810 on 02/17/1995. This new platform will replace the model originally cleared under K932810.

The device is a Hi-Lo multi-function physical therapy table as defined under 21 CFR 890.5880. Neither the proposed device nor the predicate device provides heat.

The proposed device differs from the predicate device in that it utilizes precision pneumatic actuators for distraction force and positioning rather than electric motors that were used on the predicate. The height adjustment of the proposed device is performed using the same electric motor as the predicate.

The proposed device has a new, optional automatic cycling mode intended to provide intermittent distraction and flexion.

Additionally, the AIR-FLEX with AUTO-DISTRACTION can be configured with up to four pneumatically dropped sections including cervical[1] (straight down and forward motion), thoracic, lumbar and pelvic. Each drop is activated by pressing a clearly marked button and is executed via a foot pedal.

An Air-thoracic Breakaway (with release) allows for a thoracic recoil movement and features an adjustable air tension spring controlled by a foot pedal allowing the spring to lock at any point down to 5.5 inches. This allows the use of the table with patients with large abdominal areas. The Air-Breakaway can be combined with thoracic and lumbar drop.

The proposed device can be fitted with an elevation headpiece. This raises up to 5 inches and is fitted with a tilting section. Manual or Air-activated drops can be added as options.

The activation of the selected drop can be made by footswitches or optional cocking foot strips. The AIR-FLEX with AUTO-DISTRACTION table is configured to match the owner's preferences.

The optional Auto-Flex allows the therapist to treat patients manually (for which the AIR-FLEX table is already cleared) or easily switch to AUTO-FLEX for motorized flexion. The stroke (controls the amount of flexion) can be adjusted.

The patient lies prone on the treatment surface and the patent is secured around the waist using a seat-belt type strap with quick release buckle to the stationary part of the table. The ankles are secured using straps to the movable part of the table. Once the therapist is sure that the patient is properly secured, the therapist unlocks the movable section and sets the distraction force, which is read on a gauge on the table. The therapist has the option to perform manual cycling and, where the table is configured with the automatic cycling module, can now set the overall treatment time, relax level, the rate to increase, time to hold (Pull Time) and the time to rest (Rest Time).

[1] *The cervical headpiece is also available with a manual drop.*

9.1 Indications for Use

The Air-Flex is a multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion and muscle relaxation therapy.

9.2 Technological Characteristics

The proposed device is AC powered and incorporates electrical isolation via transformers and power supplies to bring the voltage for motors, valves and switches to 24 Volts D.C Safety Extra Low Voltage (SELV) in the same manner as the original Air-Flex table originally cleared under K932810 on 02/17/1995.

The proposed device allows automatic cycling of the distraction force from the set value to a lower (Rest) value and back again in a specific amount of time with a settable pause (Hold) time. The automatic cycling is microprocessor controlled.

Distraction force for the proposed device is provided by a pneumatically (air) powered linear actuator that is very quiet and produces almost no vibration. The total amount of distraction force is the same as the predicate device. A small air compressor charges a 2 liter air reservoir that provides air to the different actuators on the table. The reservoir is fitted with an overpressure cut out as is the compressor.

A precision, high reliability load cell, rated for many times more force than the device will produce, provides force feedback to the microprocessor and this is used to measure the distraction force applied to the patient.

The proposed device is equipped with a hand-held cut-out switch which is held by the patient during the treatment time. If the patient feels discomfort and presses the cut-out switch, the treatment is immediately aborted and the traction force bleeds off gradually. The action of pressing the cut-out switch overrides all other functions. An alarm will sound whenever the button of the cut-out switch is pressed. The treatment cannot be started until the cut-out switch is attached to the equipment. If for any reason the switch or cable are defective, the treatment cannot be started.

10. Standards

10.1 Section 514 Performance Standards

There are no known mandatory Standards for this type of device

10.2 Consensus Standards

The proposed device is designed to comply with the following Consensus Standard:

STANDARD NO.	TITLE
IEC 60601-1	Medical Electrical Equipment- Part 1: General Requirements for Safety

11.0 Predicate Device

510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
K932810	Air-Flex	Hill Laboratories

11.1 Substantial Equivalence (SE) Rationale

The proposed modified device shares the same or similar basic characteristics and the same general use in physical medicine as the predicate device.

The predicate device provides manually-controlled distraction. The new device requires the therapist to manually set the upper distraction force as before but can automatically cycle between a lower force and the original force set by the therapist.

The predicate device requires the therapist apply the amount of flexion and to manually cycle the therapy. This can cause fatigue to the therapist. The Auto-Flex option allows the therapist to set the speed, number of cycles and amount of flexion. The new device automates a process that is already performed by the therapist and alleviates the fatigue.

The source of energy to provide distraction motion is electric on the predicate device and pneumatic on the new device. Both provide linear motion that is controlled by a force feedback mechanism linked to an industrial grade load cell (reliable and robust). The force feedback mechanism (load cell) is the same for the proposed modified device and the predicate.

The materials used in construction of the new device, including the frame and upholstery are the same or similar. The product code and overall intended use is the same as the predicate device. There are no new issues of safety and effectiveness posed by the new device. The risks posed by the difference in technology between the proposed modified device and the predicate are no greater than the legally marketed device.

The labeling for the new device is the same as the cleared device.

Therefore the new device is considered by Hill Laboratories to be Substantially Equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Frazer, Pennsylvania 19355

DEC 14 2006

Re: K063034
Trade/Device Name: Air-Flex with Auto-Distraction
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: Class II
Product Code: JFB
Dated: November 21, 2006
Received: November 27, 2006

Dear Ms. Aller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) No. If known K063034

Indications For Use statement

Device Name: Air-Flex with Auto-Distraction

Indications For Use:

The Air-Flex is a multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion and muscle relaxation therapy.

This device is for prescription use only.

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (Per 21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063034